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Page : 4 of 9

Attorney's Docket No.: 19758-0002US1 / OSP-18668

Amendments to the Drawings:

Attached is a replacement sheet of drawings including better quality reproductions of FIGS. 5A, 5B, and 5C, which have been prepared from electronic data of the drawings accompanying the original U.S. drawings. The replacement drawings of FIGS. 5A, 5B, and 5C also correspond to the original FIG. 5 of the Japanese priority application.

Attachments following last page of this Amendment:

Replacement Sheet (1 page)
Annotated Sheet Showing Change(s) (1 page)

REMARKS

Claims 1-9 are pending in the application. Claim 7 is currently amended. Claims 1-3, 8, and 9 are original. Claims 4-6 are cancelled, without prejudice. Claims 1-3 and 7-9 are presented for further consideration. Claims 1 and 7 are independent.

In order to obtain benefit of priority from Japanese Application No. 2003-78977, filed on March 20, 2003, and to remove Hoshino et al. (EP 1,344,827), cited in the Office Action, as a reference, submitted herewith is an English-language translation of the certified priority document (Japanese Patent Application No. 2003-78977). Submitted with the translation is a statement, signed by the translator, that the translation is the certified priority document is accurate.

Applicants do not agree that the signed inventor declaration submitted in this application is defective. In particular, we note that the "Combined Declaration and Power Attorney" found at the PAIR web site (filed June 20, 2006, copy attached) clearly identifies the application number and filing date of the International application (PCT/JP2003/17020, filed December 23, 2003) of which the present application is a 371 national stage. The declaration and application were accordingly accepted (see Notice of DO/EO Acceptance, mailed May 3, 2006, copy also attached).

In response to the objection under 37 CFR 1.83(a) to FIG. 5C of the drawings, submitted herewith is a replacement sheet of drawings including better quality reproductions of FIGS. 5A, 5B, and 5C. The replacement drawings have been prepared from electronic data of the drawings accompanying the original U.S. drawings at filing. These replacement drawings of FIGS. 5A, 5B, and 5C also correspond to the original FIG. 5 of the Japanese priority application. No new matter has been introduced.

Claims 1-3 and 7-9 stand are rejected under 35 USC §102(b) as being anticipated by Fenn et al. WO 1998/004147¹ as evidenced by Chao et al. ("Structure-function relationship in the

¹ Fenn et al. is incorrectly identified as "Tsuda et al." by the Examiner.

globular type III antifreeze protein": Identification of a cluster of surface residues required for binding to ice." *Protein Science*: Vol. 3, 10, pages 1760-1769 (1994)). Claims 1-3 and 7-9 stand rejected under 35 USC §102(b) as being anticipated by Clemmings U.S. 5,620,732 as evidenced by Chao et al. Claims 1-9 stand rejected under 35 USC §102(b) as being anticipated by, or, in the alternative, under 35 USC §103 as being obvious and therefore unpatentable over, Warren et al. U.S. 5,118,792 in view of Chao et al. These rejections are respectfully traversed.

Claims 1-9 also stand rejected under 35 USC §103 as being obvious and therefore unpatentable over Hoshino et al. EP 1,344,827, published September 17, 2003. The examiner noted that this last reference has an effective date after the priority date of the present application, and could be removed upon submission of a certified English-language translation of the priority document. As indicated above, the necessary translation and certificate are submitted herewith to remove this reference.

With respect to claim rejections based on 35 USC 102 and/or 103, the Applicants cannot accept these rejections since none of WO 1998/004147 (Fenn et al.), US 5,620,732 (Clemmings et al.), and US 5,118,792 (Warren et al.) discloses or suggests Applicant's method for inhibiting "freeze concentration" of a substance other than water molecules contained in a hydrous material by means of the antifreeze protein (hereinafter, referred to as "AFP"), which is disclosed in the present invention. In the following paragraphs, the reasons for the patentability of the present invention over the references are described.

First of all, it is necessary to explain that the process of freezing a hydrous material can proceed via Process 1 or via Processes 1 and 2 described below.

Process 1: Natural occurrence of ice nucleation particles (single crystals of ice) and crystal growth.

Process 2: Formation of lump of ice caused by "combination" of the ice nucleation particles themselves generated in Process 1.

Freeze concentration is a phenomenon caused only by Process 2. When freeze concentration occurs as a result of Process 2, which proceeds using only water molecules in a hydrous material, all substances other than water molecules are excluded in a lump of ice by

means of formation and development of a continuous freeze surface, and accumulate in places other than those where the lumps of ice are formed in the hydrous material. Thereby, the substances other than water molecules are concentrated.

Therefore, freeze concentration depends on the transfer rates of freeze surfaces or surface conditions (turbulent conditions of the surfaces), and does not directly relate to ice crystal size or an aspect ratio of the ice crystal.

Here, it is important that Process 1 be a natural phenomenon which inevitably occurs during freezing, but in contrast, Process 2, and the freeze concentration associated therewith, do not inevitably occur. Therefore, Process 1 is independent with respect to Process 2, and does not necessarily involve Process 2. It is apparent that Process 2 does not necessarily occur, since technologies such as a suspension crystallization method (for example, Halde, R.; "Concentration of Impurities by Progressive Freezing," Water Research, 14, 575-580 (1979)) and a surface advance freeze concentration method (for example, A. Matsuda, K. Kawasaki, and H. Kadota; "Freeze Concentration with Supersonic Radiation under Constant Freezing Rate – Effect of Kind and Concentration of Solutes-", J. Chem. Eng. Japan, 32, 569-572 (1999)) were developed "in order to purposely cause freeze concentration."

In addition, it is commonly known that ice crystals do not inevitably combine with each other, since it is difficult to combine snow powders or fine ice powders in some cases, even if they are strongly gripped. It is believed that no one skilled in the art would doubt that the occurrence of Process 2 greatly depends on temperature, humidity, and components contained in a hydrous material (sugars, alcohols, fine particles, or the like).

In Applicant's present invention, a "technology for inhibiting combination of plural ice crystals" which occurs in Process 2 was completed based on the examples described in the specification of the present application as originally filed.

In contrast, all of the cited references merely relate to "technologies for inhibiting growth of ice crystals" which occurs in Process 1.

Therefore, while the present invention relates to a technology for inhibiting Process 2, all of the cited references relied upon for rejection relate to technologies for inhibiting the growth of

ice crystals specified in Process 1, and therefore fail to verify the effects of inhibiting Process 2. This is clear, since the term “freeze concentration” is not described at all in the cited references.

Therefore, it cannot be accepted that the cited references, which fail to verify the effects of inhibiting Process 2, will have effect for inhibiting not only Process 1, but also Process 2.

The specific differences between the present invention and each of WO 1998/004147 (Fenn et al.), US 5,620,732 (Clemmings et al.), and US 5,118,792 (Warren et al.) will now be described:

WO 1998/004147 (Fenn et al.) relates to a process for the production of a frozen food product comprising AFP, wherein the conditions are chosen such that the ice-crystals in the product have an aspect ratio ranging from 1.1 to 1.9. In addition, US 5,620,732 (Clemmings et al.) relates to a method for minimizing ice crystal size in a frozen composition by adding AFP to a hydrous mixture. As described above, freeze concentration depends on the transfer rates of freeze surfaces or surface conditions (turbulent conditions of the surfaces), and does not directly relate to an ice crystal size or an aspect ratio of the ice crystal, as specified in the aforementioned references. Therefore, the aforementioned references fail to disclose, or to suggest, that AFP can inhibit freeze concentration.

In addition, WO 1998/004147 (Fenn et al.), and US 5,620,732 (Clemmings et al.) encompass a method of producing a frozen product, such as ice cream. In general, ice cream is a product prepared by stirring raw materials such as milk and the like while cooling so that the mixture includes air to form a mixture in the form of a cream (emulsion), and, subsequently, freezing the emulsified mixture. As described above, in the preparation of ice cream, the emulsion prepared by stirring the raw materials so that the emulsion contains air is frozen. For this reason, regardless of the presence or absence of AFP, freeze concentration of the materials in the ice cream (hydrous material) can be controlled. Therefore, on the basis of the references disclosing a method of producing ice cream, a person skilled in the art could not have conceived of the novel use of AFP of inhibiting freeze concentration of a substance other than water molecules in a hydrous material. Consequently, the rejection could only have been issued by application of impermissible hindsight by the Examiner.

US 5,118,792 (Warren et al.) relates to a fusion protein consisting essentially of a polypeptide exhibiting ice crystal growth suppression activity and a heterologous protein domain. As described above, US 5,118,792 (Warren et al.) provides "technologies for inhibiting growth of ice crystals" occurring in Process 1. Therefore, as above, US 5,118,792 (Warren et al.) fails to teach, or to suggest, that AFP can inhibit freeze concentration.

As described above, the present invention is not taught, nor is it suggested in the aforementioned cited references, whether taken alone, or in any proper combination, and therefore could not have been easily created by a person skilled in the art based on the aforementioned cited references. We submit that the Applicants' above claims are distinguished over the cited references, and, therefore, are patentable.

On this basis, we submit further that this application is now in condition for allowance. Early favorable action is solicited.

Please apply any charges, including for extensions, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

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